UNITED STATES DISTRICT COURT

FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ex rel., TERESA ROSS, Plaintiff, v. GROUP HEALTH COOPERATIVE, et al., Defendants.	Civil Action No. 12-CV-0299 (WMS)

MEMORANDUM OF LAW IN SUPPORT OF MOTION OF DEFENDANTS INDEPENDENT HEALTH CORPORATION, INDEPENDENT HEALTH ASSOCIATION, DXID, LLC, JOHN HAUGHTON, AND BETSY GAFFNEY TO DISMISS THE AMENDED COMPLAINT

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I. INTRODUCTION

This non-intervened False Claims Act ("FCA") suit seeks to manufacture a fraud case out of an honest disagreement about the meaning and applicability of unclear, complex, and often conflicting industry-wide coding criteria—specifically, how to interpret a nonbinding Medicare training guide. Plaintiff Teresa Ross ("Relator") alleges that her former employer, Group Health Cooperative ("GHC"), on the basis of coding advice allegedly provided by its consultant, DxID, submitted diagnosis codes to the Centers for Medicare and Medicaid Services ("CMS") that she believes are inconsistent with her interpretation of certain medical coding guidelines listed in that guide. She further alleges that it is "highly likely" that Independent Health, a health insurer with no affiliation to GHC, did the same.

This interpretive dispute is entirely outside the purview of the False Claims Act, which exists to punish individuals who deliberately set out to "defraud the Government," *Allison Engine Co. v. U.S. ex rel. Sanders*, 553 U.S. 662, 672 (2008), not to provide a vehicle for dissatisfied employees who wish to challenge their employers' interpretations of ambiguous, subregulatory guidance manuals. *See Schindler Elevator Corp. v. U.S. ex rel. Kirk*, 563 U.S. 401, 413 (2011) (the FCA was intended to "encourag[e] private persons to root out fraud," not to incentivize "parasitic lawsuits"); *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 2003 (2016) ("The False Claims Act is not . . . a vehicle for punishing garden-variety breaches of contract or regulatory violations."). For that reason, courts repeatedly have rejected claims like the ones pressed by Relator in this suit—even in cases where, *unlike* here, the government determined that the case had sufficient merit to warrant intervention. These cases illustrate that Relator's Amended Complaint ("AC") suffers from four independent defects, each of them fatal.

First, while Relator repeatedly asserts that the coding policies DxID allegedly recommended violated "CMS rules," AC ¶¶ 83, 85, 90, 92, the Amended Complaint conspicuously

fails to cite a single CMS regulation setting forth the coding criteria on which Relator relies. In fact, no such rules exist. Instead, as the Amended Complaint eventually makes clear, Relator's theory rests entirely on a single informal Medicare training manual, the Participant Training Guide. This is a fundamental failure, because only statutes, regulations, or contract provisions can create legal obligations of the sort necessary to impose FCA liability. *See Christensen v. Harris Cty.*, 529 U.S. 576, 587 (2000); *U.S. ex rel. Mikes v. Strauss,* 274 F.3d 687, 697 (2d Cir. 2001). Informal guidance documents, not promulgated under notice-and-comment rulemaking, cannot impose legal obligations enforceable under the FCA.

Second, and just as fundamentally, Relator's interpretation of the Participant Training Guide is wrong as a matter of law. The text of this document simply does not support Relator's view, and CMS itself, which authored the Guide, does not interpret the Participant Training Guide as imposing the requirements Relator alleges. On the contrary, CMS directs its own coders to use the very coding criteria Relator challenges when CMS conducts audits of health plans looking for potential overpayments. At the very least, Defendants' interpretation of the Participant Training Guide was objectively reasonable, and it is well established that the FCA does not penalize "'reasonable, but erroneous, interpretations of a defendant's legal obligations.'" *U.S. ex rel. Streck v. Allergan Inc.,* 746 F. App'x 101, 106 (3d. Cir. 2018) (*quoting U.S. ex rel. Purcell v. MWI Corp*., 807 F.3d 281, 287-88 (D.C. Cir. 2015)).

Third, Relator fails adequately to allege that Defendants' failure to comply with her interpretation of the training manual amounted to "material" misconduct—*i.e.,* misconduct that altered the government's ultimate payment decision. *Universal Health Servs*., 136 S. Ct. at 2003. This failure is especially revealing given that the government has spent over seven years investigating Relator's allegations; and yet Relator does not claim that CMS *ever* refused to make

risk adjustment payments to Defendants as a result of the conduct she complains about. Indeed, it would be absurd for Relator to allege that Defendants' coding policies caused CMS to make an overpayment when CMS directs *its own auditors* to apply those very same policies when determining the validity of diagnosis codes a plan has submitted.

Finally, Relator utterly fails to plead fraud with the particularity demanded by Rule 9(b). Relator was an employee of GHC, and has never had any employment relationship or interaction with either of the two Independent Health entities she names as defendants. Relator thus has no idea what coding policies either entity adopted. Her entire claim against Independent Health is based on her conjecture that it is "highly likely" that one of the two Independent Health companies (she does not specify which) adopted some of the same coding policies that DxID allegedly recommended to GHC. Rule 9(b) exists precisely to prevent these sorts of "fishing expeditions" by individuals with no firsthand knowledge hoping to discover evidence of some yet "unknown[] wrong." *Johnson v. Univ. of Rochester Med. Ctr*., 686 F. Supp. 2d 259, 267 (W.D.N.Y. 2010); *Madonna v. United States*, 878 F.2d 62, 66 (2d Cir. 1989). Nor does the complaint contain any allegations, let alone particularized ones, that any of the undersigned defendants believed that the coding policies Relator challenges were unlawful. This pleading failure is fatal, particularly in the FCA context, which demands not only particularized allegations of the circumstances constituting fraud, but also particularized allegations that "give rise to a strong inference of fraudulent intent." *U.S. ex rel. Tessler v. City of New York*, 712 F. App'x 27, 30 (2d Cir. 2017). Lastly, the complaint contains no particularized allegations at all against Dr. John Haughton or Betsy Gaffney, the two named individuals, improperly lumping them together with DxID, and entirely failing to specify—as Rule 9(b) requires—how each defendant's conduct and intent violated the False Claims Act.

Each of these four failures independently requires dismissal.

II. BACKGROUND

A. Regulatory Background

CMS, a division of the Department of Health and Human Services ("HHS"), is responsible for administering the Medicare Program. Under Parts A and B of the Medicare Program, known as "traditional" Medicare, CMS directly reimburses healthcare providers using a fee-for-service ("FFS") payment system. *See* 42 U.S.C. § 1395c *et seq.* (Part A, covering inpatient care); *id.* § 1395j *et seq.* (Part B, covering outpatient care). In 1997, Congress created Medicare Part C, known as "Medicare Advantage" (or "MA" for short), as an alternative to traditional Medicare. *See id.* § 1395w-21 *et seq*. Rather than paying for specific items and services, the Medicare Advantage program pays private insurance plans to take on the risk associated with covering Medicare beneficiaries. The coverage plans offered by these insurers are known as Medicare Advantage plans, or "MA plans" for short.

When a beneficiary enrolls in a Medicare Advantage plan, his or her insurance provider receives a fixed monthly payment from the government (often referred to as a "capitation payment"); in exchange, the insurer is responsible for paying for that beneficiary's covered healthcare costs, whatever those end up being. *See generally id*. § 1395w-23. The plan thus has an incentive to manage the beneficiary's care in a manner that promotes long-term health and provides better services, all at the same cost as traditional Medicare.

To ensure that MA plans are paid appropriately for the risk they take on, Congress requires CMS to ensure that there is "actuarial equivalence" between the traditional fee-for-service Medicare program and the Medicare Advantage program. *See id.* § 1395w-23(a)(l)(C)(i). As HHS has described it, this means that there must be equivalence "between the average payments that CMS would expect to make on behalf of a given beneficiary under traditional fee-for-service (FFS) Medicare and the payments made to Medicare Advantage (MA) insurers for covering an individual

with those same characteristics." Federal Defendants' Cross-Motion for Summary Judgment at 8, *UnitedHealthcare Ins. Co. v. Azar*, No. 16-cv-157 (D.D.C. Dec. 4, 2017), Docket No. 57-1.

To ensure this actuarial equivalence, CMS must adjust Medicare Advantage payments based on the risk that different Medicare Advantage beneficiaries present. *See* 42 U.S.C. § 1395w-23(a)(1)(C). For example, a 65-year-old woman with no chronic health conditions would be unlikely to incur significant health expenditures during a year, and would thus cost the fee-for-service program relatively little in direct fees; accordingly, a Medicare Advantage insurer should receive lower than average payments for insuring her. In contrast, a 93-year-old man with diabetes and multiple sclerosis likely would require significant interventions, which would cost the fee-for-service program more in direct fees; accordingly, a Medicare Advantage insurer would receive higher payments for such a beneficiary.

CMS conducts risk adjustment by calculating a total "risk score" for each patient. CMS begins with data that is readily available to it—the costs it incurs for the care of tens of millions of beneficiaries in the traditional fee-for-service Medicare program, as well as the information it has about their healthcare conditions. *See UnitedHealthcare Ins. Co. v. Azar,* 330 F. Supp. 3d at 173, 178-79 (D.D.C. 2018) (describing this process). It then uses statistical regression techniques to associate medical costs across the fee-for-service program with the demographic status of individual beneficiaries (age, gender, and the like) and the "diagnosis codes" it collects for those beneficiaries during the claims submission process. *See id.* These diagnosis codes are numerical codes submitted by healthcare providers that designate the conditions with which a patient has been diagnosed.

Once CMS has calculated how a given diagnosis code or demographic status affects the risk of increased costs in the traditional Medicare program, it then uses those calculations to

determine the likely risk posed by a Medicare Advantage plan's beneficiaries. The "average beneficiary" is given a risk score of 1.0, which CMS then adjusts upwards or downwards in accordance with an individual's demographic information and diagnoses. *See id.* at 178-79. "For example, if a beneficiary has a condition that CMS has determined based on its Medicare data increases average costs by 20%, that person will have an adjusted risk score of 1.2 and the Medicare Advantage payment rate applicable to that person will be set at 120% of the average benchmark rate." *Id*. at 179. Hence, a plan that enrolls beneficiaries with higher risk scores will receive larger insurance premiums from the federal government, because it incurs more financial risk in agreeing to cover their care. *See id.*

In sum, unlike physicians operating under a fee-for-service model (who are paid after the fact for treatment they actually provided), MA plans are paid for the *future* risk they will incur in insuring a beneficiary during the contract year. Because having a health condition, such as diabetes or a history of prior heart attacks, makes a beneficiary more likely to incur health expenses in the subsequent year—whether or not the beneficiary actually received treatment for those conditions in the prior year (indeed, a beneficiary who did not receive treatment for his condition may be at an even greater risk)—the key issue for purposes of payment is knowing what conditions the beneficiary had in the prior year, not the treatments he received. So long as "at least one" instance of a diagnosis code is supported, the plan is entitled to an upward adjustment of its beneficiary's risk score, even if all other reported instances of the same diagnosis code are unsupported.[1]

[1] *See* CMS*, Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits, Executive Summary* at 3 (Oct. 26, 2018), https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Excecutive-Summary.pdf ("FFS Study Executive Summary").

Because the risk-adjustment process is based in large part on data obtained from diagnosis codes, the coding process plays an important role in the operation of the Medicare Advantage program. With respect to the health status of their own beneficiaries, plans annually submit to CMS diagnosis codes they have gathered from claims submissions they received from providers as well as from their own review of their providers' medical charts. The set of numerical codes used to report these conditions is the International Classification of Diseases (ICD), a classification system whose relevant edition, "ICD-9-CM," contains over 100,000 codes, each corresponding to a different condition or health status. HHS adopted the ICD-9 system—along with the Official ICD-9-CM Guidelines for Coding and Reporting ("ICD-9 Guidelines")—as the nation's "standard medical data code sets" up until 2015 (after which time it was superseded by a newer edition, the ICD-10-CM). *See* 45 C.F.R. § 162.1002(a)(1)-(2); 45 C.F.R. § 162.1002(b)(1).

The ICD-9-CM classification system tells providers what numerical code to use for a given medical condition (for example, that the code for type II diabetes without complications is 250.00). The ICD-9 Guidelines are a set of rules "developed to assist both the healthcare provider and coder in identifying those diagnoses and procedures that are to be reported" in a way that "complement[s] the official conventions and instructions provided within the ICD-9-CM itself." 2010 ICD-9 Guidelines at 1.[2] The Guidelines are updated annually by CMS and the National Center for Health Statistics ("NCHS") in conjunction with two private entities, the American Hospital Association ("AHA") and the American Health Information Management Association ("AHIMA"), and are largely devoted to providing a more granular explanation of the applicability of particular codes.

[2] CMS has published the ICD-9 Guidelines online. The 2010 edition can be found at https://web.archive.org/web/20100923053529/https://www.cdc.gov/nchs/data/icd9/icdguide10.pdf.

The ICD-9 coding set itself does not instruct coders on *how* to decide whether a medical record entry provides sufficient support for assigning a particular diagnostic code. For instruction on that front, coders must consult a variety of professional guidelines and subregulatory training manuals that provide supplemental coding advice. Most of these supplements—such as the AHA's ICD-9 Coding Clinic for hospitals, or the physician-coding training courses provided by the American Academy of Professional Coders—are written and sold by private entities. Others—such as the Risk Adjustment Training for Medicare Advantage Organizations Participant Guide ("Participant Training Guide")[3]—are issued by CMS.

CMS encourages providers to consult these and similar guidelines, *see* Participant Training Guide at 6-13, but emphasizes that, other than the ICD-9 Guidelines, none of these subregulatory training manuals is "official" (and, thus, is not authoritative). *See* 2010 ICD-9 Guidelines at 1 ("Only this set of guidelines, approved by [CMS, NCHS, the AHA, and AHIMA], is official."). Even CMS's own training manuals, including the Participant Training Guide, do not purport to be comprehensive resources, nor do they claim to impose special coding criteria rules specific to MA plans.[4] On the contrary, the Participant Training Guide expressly states (at 6-5) that the MA program follows the "Standard ICD-9-CM coding practices," and thus urges MA plans to follow the industry-wide set of professional guidelines listed at the end of the training presentation.

In addition to the private and subregulatory guidances available within the industry, CMS has issued a set of internal risk-adjustment coding guidelines, whose content has varied over time,

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[3] The 2008 edition of the Participant Training Guide, on which Relator relies, can be found online at https://www.csscoperations.com/Internet/Cssc3.Nsf/files/participant-guide-publish_052909.pdf/$File/participant-guide-publish_052909.pdf ("Participant Training Guide").

[4] *See* Participant Training Guide at 6-1 ("It is neither the intention of this [risk-adjustment] module nor the purpose of this training [manual] to provide diagnostic coding training."); *id.* at 6-13 (directing readers seeing coding training to consult one of several other resources, including private coding clinics and "local community and 4-year college[] courses").

for its own coders to use when conducting Risk Adjustment Data Validation ("RADV") audits of MA plan diagnostic code data. To assess whether medical records adequately support the enrollees' diagnosis codes, and thus determine whether it believes the plan has been paid appropriately, CMS provides its auditors with manuals called "Risk Adjustment Data Validation Medical Record Intake Process and Guidance to Coders," or "RADV Guides." These manuals are designed to outline general coding principles for the auditors to use in assessing whether the diagnosis codes submitted by a plan to CMS as part of its risk adjustment data are medically supported.

These RADV Guides reflect CMS's own, internal interpretation of the ICD-9 coding guidelines as they apply in the risk-adjustment context, and provide its more detailed application of the training more briefly set forth in the Participant Training Guide. The RADV Guide applicable to the 2011 contract year, which was disseminated by CMS to all Medicare Advantage Organizations whose 2011 contracts were selected for a RADV audit to inform MA Plans of the coding criteria that CMS would utilize in validating their diagnosis code data, is attached as Exhibit A to the accompanying Meron Affirmation ("2011 RADV Guide").[5]

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[5] This Court may consider documents subject to judicial notice at the motion-to-dismiss stage without converting the motion to dismiss into one for summary judgment. *Staehr v. Hartford Fin. Servs. Grp., Inc*., 547 F.3d 406, 425-26 (2d Cir. 2008). Agency-issued documents, such as the RADV Guides, are judicially noticeable so long as the document's authenticity is "not subject to reasonable dispute because [it] . . . can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned." *Richardson v. New York City Bd. of Educ*., 711 F. App'x 11, 13 (2d Cir. 2017) (quoting Fed. R. Evid. 201); *see also* Fed. R. Evid. 902(5) (a "book, pamphlet, or other publication purporting to be issued by a public authority" is self-authenticating). Accordingly, courts routinely take judicial notice of agency guidance documents—particularly where, as here, those documents are offered for the legal significance of the guidance they provide, rather than for proof of an extrinsic or historical fact contained therein. *See, e.g., Gleave v. Graham*, 954 F.Supp. 599, 605 (W.D.N.Y. 1997) (taking judicial notice of internal Bureau of Prison "Program Statements") (aff'd 152 F.3d 918 (2d Cir.1998)); *In re Frito-Lay N. Am., Inc. All Nat. Litig*., No. 12-MD-2413, 2013 WL 4647512, at *3-*4 (E.D.N.Y. Aug. 29, 2013) (taking judicial notice of various "policy and guidance documents" issued by federal agencies); *Frith v.*

B. Relator's Allegations

Relator Teresa Ross filed this *qui tam* action on April 11, 2012, purporting to bring claims on behalf of the United States. Docket No. 1. As required under the FCA, her complaint was filed under seal and served on the federal government. *See* 31 U.S.C. § 3730(b). She amended her complaint in 2016, again under seal. Docket No. 32 ("Amended Complaint" or "AC"). After the government spent approximately seven years investigating Relator's allegations and declined to intervene, her case was unsealed. *See* Docket No. 63. Relator's allegations center on a series of disagreements between herself and her former employer, GHC, about the proper interpretation and application of informal coding guidelines—specifically, the Participant Training Guide.

GHC was a non-profit Seattle-based insurance company that operated Medicare Advantage Plans in Washington and Idaho, AC ¶ 17, and was subsequently acquired by another entity. Relator, who formerly worked as GHC's Director of Risk Adjustment Services, *id.* ¶ 18, believes that the Participant Training Guide imposes binding "CMS rules" on MA plan providers, *id.* ¶ 118. She alleges that—by adopting an interpretation of the Participant Training Guide that differs from her own—GHC, acting with coding advice input from Defendant DxID, submitted diagnosis codes to CMS that violated those rules, *id.* ¶ 90, in a way that gives rise to liability under the False Claims Act.

According to the Amended Complaint, Relator's disagreements with her supervisors at GHC extended back to at least 2007. *Id.* ¶ 81. Tensions peaked in 2011, when GHC decided to hire an external risk-consultant, DxID, to conduct a retrospective review of GHC's past risk-adjustment claims for the years 2010 and 2011, *id.* ¶¶ 87-88, 96, 131. This review process

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Hill, No. 07-5899, 2009 WL 3073716, at *16-17 & n.10 (S.D.N.Y. Sept. 23, 2009) (taking judicial notice of "internal ATF guidelines submitted by [defendant]" in granting motion to dismiss).

"bypass[ed]" Relator's own department, further straining Relator's already tense relationship with her supervisors. *Id.* ¶ 98.

DxID ultimately concluded that some of the coding policies created and implemented by Relator were overly restrictive, and therefore were likely to cause GHC to systematically underreport patients' health conditions. In the course of conducting its review, DxID explained its view to GHC, and "asked GHC's leadership to approve or reject certain coding policies," such as coding based off of diagnoses in "problem lists" embedded within a patient's medical record. *Id.* ¶¶ 99, 105. GHC approved many of these coding policies, siding with DxID's understanding of coding methods over Relator's. Where GHC did not approve the policy, DxID did not implement it. *See id.* ¶ 137 (explaining that GHC rejected one of DxID's proposed policies for coding a patient's history of heart attacks).

Relator alleges that some of these policies contravened advice provided in the Participant Training Guide. For example, Relator believes that the Participant Training Guide bars MA plans from relying on "problem lists" to support a risk-adjustment claim unless the patient received treatment for that condition in the same visit. *Id.* ¶ 116. She also identifies a smattering of individual diagnosis codes, none of which pertain to Independent Health beneficiaries, that she claims were submitted without necessary documentation. *Id.* ¶¶ 140-47. Her allegations, however, are limited to individual encounters—she does not address whether the same diagnosis code was submitted for the same beneficiary following a different encounter within the relevant year, or by a different provider, or whether that other diagnosis code was properly documented. In other circumstances, Relator identifies coding criteria that she disagrees with, but does not cite any authority—regulatory, subregulatory, or otherwise—explaining why those criteria are legally

improper. *See, e.g.*, AC ¶¶ 153-54 (alleging that Independent Health and DxID improperly asked physicians to clarify diagnosis codes after the applicable date of treatment).

In addition to GHC and DxID, Relator also brings claims against Independent Health Association ("IHA") and Independent Health Corporation ("IHC"). IHA is a nonprofit company that operates a Medicare Advantage Plan in the Western New York area. IHC is a for-profit, wholly owned subsidiary of IHA. DxID is a wholly owned subsidiary of IHC. Like GHC, IHA relied on DxID for coding services, although Relator does not claim to have interacted with—or witnessed interactions involving—either Independent Health entity *at all*.

Finally, the Amended Complaint also names as defendants two individuals associated with DxID, Dr. John Haughton (DxID's Consulting Risk Adjustment Advisor) and Betsy Gaffney (DxID's co-CEO) (together, the "Individual Defendants"). As with IHA and IHC, the Amended Complaint does not contain detailed allegations regarding either of these Individual Defendants. Relator does not plead that she ever interacted with any defendant other than GHC and DxID, nor does she allege having witnessed any improper conduct by Independent Health or the Individual Defendants.

There is no corporate affiliation or relationship between Independent Health Association and GHC—each insurer operates separate plans at opposite ends of the country. The only commonality between the two entities is that each employed DxID, a subsidiary of IHC, to provide it with coding advice and to review certain medical records.

III. STANDARD OF REVIEW

To survive a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Wood ex rel. U.S. v. Applied Research Assocs.* ("*ARA*"), 328 F. App'x 744, 746 (2d Cir. 2009) (*quoting Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). "'The plausibility

standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully.'" *Id.* at 746-47 (*quoting Iqbal*, 556 U.S. at 678). A statement of facts that "merely creates a suspicion [of] a legally cognizable right of action," is insufficient, *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007), and "stops short of the line between possibility and plausibility of entitlement to relief," *ARA*, 328 F. App'x at 747 (*quoting Iqbal*, 556 U.S. at 678).

In addition, Rule 9(b) requires that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b); *see also, e.g.*, *U.S. ex rel. Ladas v. Exelis, Inc*., 824 F.3d 16, 26 (2d Cir. 2016) (explaining that Rule 9(b)'s requirements must be "rigorously enforce[d]" in FCA cases). In the FCA context, Rule 9(b) requires a relator to allege both fraudulent intent and materiality with particularity. *See Grabcheski v. Am. Int'l Grp*., *Inc.*, 687 F. App'x 84, 87 (2d Cir. 2017) (materiality); *U.S. ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 694 (S.D.N.Y. 2018) (*citing Shields v. Citytrust Bancorp, Inc*., 25 F.3d 1124, 1129 (2d Cir. 1994)) (fraudulent intent).

IV. ARGUMENT

The False Claims Act imposes severe penalties—including treble damages plus civil penalties of up to $10,000 for each false claim—on any individual who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
> (C) conspires to [violate (A), (B), or (G); or] . . .
> (G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government[.]

31 U.S.C. § 3729(a); *Universal Health Servs., Inc.*, 136 S. Ct. at 1996. Private parties, known as "relators," who initiate successful FCA suits receive between fifteen and thirty percent of the ultimate financial award or settlement. 31 U.S.C. § 3730(d)(1)-(2).

To state a claim under the FCA, a relator must show that "the defendants (1) made a claim, (2) to the United States Government, (3) that is false or fraudulent, (4) knowing of its falsity, and (5) seeking payment from the federal treasury." *Coyne v. Amgen, Inc*., 717 F. App'x 26, 28 (2d Cir. 2017). In addition, an "alleged misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be actionable[.]'" *Id.* at 28-29 (*quoting Universal Health Servs., Inc.*, 136 S. Ct. at 2002).

Here, Relator contends that Defendants' alleged use of certain diagnostic coding criteria violated the FCA because those techniques failed to conform with her interpretation of informal risk-adjustment coding guidelines. This argument fails for four independent reasons.

At the outset, Relator does not point to a single source that legally obligates Defendants to comply with the Participant Training Guide, or any other subregulatory training handbooks. Nor could she. The Participant Training Guide does not even purport to be comprehensive or binding, and CMS itself has acknowledged that it is not "official." *Supra* at Part II.A. This makes sense, because, under the Administrative Procedure Act, agency handbooks, manuals, or policy statements issued without notice-and-comment "lack the force of law." *Christensen*, 529 U.S. at 587. Instead, such guidance documents simply represent agencies' attempts at "explaining, interpreting, [or] defining," criteria listed in statutes, regulations, or, sometimes, other guidance documents. *Appalachian Power Co. v. E.P.A*., 208 F.3d 1015, 1020 (D.C. Cir. 2000). What's more, courts cannot rely on Medicare training guidelines relating to payment *even as interpretive rules,* because Congress has prohibited CMS from issuing any "rule, requirement, or other statement of policy (other than a national coverage determination) that establishes or changes a substantive legal standard governing the . . . payment for services . . . under [Medicare]" without first going through notice-and-comment rulemaking. 42 U.S.C. § 1395hh(a)(2). On the basis of

this statutory provision, the Supreme Court recently made clear that CMS cannot use informal manuals or guidances, whether characterized as policy statements, interpretive rules, or otherwise, to set standards relating to payment in the Medicare program. *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019).

Second, even if Defendants were somehow obligated to comply with informal training guidelines, Relator's interpretation of these guidelines is incorrect as a matter of law. Relator alleges that the Participant Training Guide barred some of Defendants' coding practices, but the text of this document and other CMS training manuals gives lie to Relator's interpretation. Instead, the text shows that DxID's interpretation of the guidance documents was correct. At the very least, DxID's interpretation was objectively reasonable, and the FCA cannot be used to penalize defendants for mistakes "made based on reasonable but erroneous interpretations of [their] legal obligations." *Purcell*, 807 F.3d at 288.

Third, Relator has not pled that Defendants' alleged failure to comply with the Participant Training Guide was "material." The FCA's "materiality standard is demanding," *Universal Health Servs., Inc.*, 136 S. Ct. at 2003, and requires a relator to allege facts showing that the supposed violations "are so central . . . that the [government] *would not have paid these claims* had it known of these violations." *Id.* at 2004 (emphasis added). Relator never alleges that the government has failed to pay a claim on the grounds that the claim submission did not comport with her interpretation of the Participant Training Guide. In fact, CMS's *own audit guidelines* expressly adopt many of the exact same coding policies that Relator describes as "fraudulent."

Finally, in a variety of ways, Relator has failed to plead her FCA claims with the particularity required by Rule 9(b). This failure is especially glaring when it comes to Relator's

allegations against IHC, IHA, and the Individual Defendants, which are entirely conclusory, speculative, and untethered from Relator's personal knowledge or experience.

Each of these defects requires dismissal of the Amended Complaint.

A. Relator Fails to Allege That Defendants Violated Any Binding Legal Obligations

Relator's theory of FCA liability—that Defendants submitted "false" claims by failing to comply with certain coding criteria—fails at the outset because Relator points to *nothing* that makes the informal coding guidelines on which she relies legally binding on Defendants. As the Second Circuit has recognized, liability for a legally false claim under the FCA must be based on a false certification of compliance with either contract terms or else a *statute* or *regulation*. *Mikes*, 274 F.3d at 697; *accord* 31 U.S.C. § 3729(b)(3) (omitting subregulatory guidance from a list of the types of authority that can give rise to a legal "obligation to pay or transmit money or property to the Government" under the False Claims Act); *see also, e.g.*, *Phoenix Baptist Hosp. & Med. Ctr. v. Heckler*, 767 F.2d 1304, 1307 (9th Cir. 1985) ("The [Provider Reimbursement Review] Manual is a guide for intermediaries in applying the Medicare statute and reimbursement regulations and does not have the binding effect of law or regulation.").

Lacking any statutory or regulatory provision that speaks directly to the requirements she asks this Court to impose, Relator relies *exclusively* on subregulatory guidance—specifically, the Participant Training Guide—in attempting to set out the criteria with which GHC and DxID allegedly failed to comply. That is not enough to support an FCA action, however, because the Participant Training Guide and similar handbooks are neither statutes nor regulations, and for that reason "'lack the force of law.'" *De La Mota v. U.S. Dep't of Educ.*, 412 F.3d 71, 79 (2d Cir. 2005) (*quoting Christensen*, 529 U.S. at 587); *see also Moore v. Apfel*, 216 F.3d 864, 869 n.2 (9th Cir. 2000) ("agency manuals lack the force of law"). Accordingly, even the Department of

Justice has recognized that it would be improper to "use its enforcement authority to effectively convert agency guidance documents into binding rules" or to "use noncompliance with guidance documents as a basis for proving violations of applicable law" in False Claims Act Cases. Mem. for Heads of Civil Litigating Components & U.S. Att'ys from Assoc. Att'y Gen., Rachel Brand, *Limiting Use of Agency Guidance Documents In Affirmative Civil Enforcement Cases* at 2 (Jan. 25, 2018), http://src.bna.com/vY4; *accord* U.S. DEP'T OF JUSTICE, JUSTICE MANUAL 1-19.000 (2018), online at https://www.justice.gov/jm/1-19000-limitation-issuance-guidance-documents-1 (same).

While these general principles that apply to any agency's guidelines are themselves fatal to Relator's claims, the Medicare Act includes an additional significant constraint on the use of these types of informal documents to establish criteria for payment in the Medicare Program specifically. In that Act, Congress expressly prohibited CMS from issuing any "rule, requirement, *or other statement of policy* . . . that establishes or changes a substantive legal standard governing . . . the payment for services . . . under [Medicare]" without first going through notice-and-comment rulemaking. 42 U.S.C. § 1395hh(a)(2) (emphasis added). In *Azar v. Allina Health Services*, 139 S. Ct. 1804 (2019), the Supreme Court explained that this requirement means that any agency pronouncement establishing a substantive standard for payment must go through notice and comment, irrespective of whether that pronouncement is styled as a manual, a guidance document, an "interpretive rule[]," or as some other "statement[] of policy." *Id.* at 1811-12. In other words, even if Relator were correct in believing that the Participant Training Guide purported to establish new rules governing when diagnosis codes may be submitted for payment, those rules would be ultra vires under *Allina Health*—because the Participant Training Guide has not gone

through notice-and-comment rulemaking and therefore cannot establish binding criteria with respect to the eligibility of particular diagnosis codes for payment.

B. Even If Informal Guidance Documents Were Binding, Those Documents Would Not Support Relator's Fraud Claim

Because informal guidelines are promulgated through a process that lacks the protections provided by notice-and-comment rulemaking, those guidelines are often unclear, incomplete, and inconsistent. CMS itself acknowledges this reality. It has emphasized that even the official ICD-9 Guidelines "are not exhaustive," and that other training resources, while often helpful, are not "official." 2011 ICD-9 Guidelines at 1;[6] *see also* 2010 ICD-9 Guidelines at 1. Similarly, the Participant Training Guide, on which Relator grounds this lawsuit, explains that "[i]t is neither the intention of this [risk adjustment] module nor the purpose of this training [document] to provide diagnostic coding training." Participant Training Guide at 6-1. Rather, the purpose of the Participant Training Guide is to "provide Risk Adjustment organizations with an introduction to diagnosis coding" in a way that helps providers apply the "official" ICD-9 Guidelines. *Id.* CMS also made clear that the coding standards it utilizes in the MA program are the "standard" official ICD-9 coding criteria—not a set of special rules created by CMS for this purpose. *Id.* at 6-5. In other words, CMS designed the Participant Training Guide as an introduction to help providers understand official coding rules, not to create or establish coding rules that did not otherwise exist.

One consequence of this dearth of formal, authoritative guidance is that coders often must make judgment calls—sometimes difficult ones—about whether assignment of a given diagnosis code is indicated by a patient's medical record. They also have to ground those judgment calls on

[6] The 2011 edition of the ICD-9 Guidelines is available online at https://www.cdc.gov/nchs/data/icd/icd9cm_guidelines_2011.pdf.

a number of different private and governmental guidance documents that are, as might be expected of informal high-level guidance, sometimes inconsistent.

Here, Relator's judgment about the meaning of certain coding guidelines is simply wrong. Further, even if this Court concluded that Relator's interpretations are correct, that conclusion would not be enough to support Relator's FCA claims. That is because, at a minimum, Defendants' interpretation of applicable coding guidelines was reasonable, and the FCA does not penalize "reasonable but erroneous interpretations of a defendant's legal obligations." *Purcell*, 807 F.3d at 288.

1. The coding policies listed in the Amended Complaint do not violate the Participant Training Guide.

The Amended Complaint focuses on three particular coding policies that Relator claims give rise to FCA liability: (1) submission of certain diagnosis codes even if a patient was not actively treated for that diagnosis during the relevant encounter; (2) submission of certain diagnosis codes supported by diagnostic testing results; and (3) use of physician query forms to clarify ambiguities in the medical record.[7] As explained below, however, none of these policies violates even informal coding guidelines.

1. *Active treatment (and reliance on "problem lists")*. The most pervasive allegation in the Amended Complaint is that plans may not submit a given diagnosis code to CMS unless the

[7] Relator also mentions that DxID "fail[ed] to delete [GHC's] previously submitted codes that were not supported by the medical record," AC ¶ 123, but never attempts to tie this failure to an FCA violation by DxID. Nor could she, because liability under the FCA requires an affirmative act and cannot be premised on failure to correct the violations of a third party. *See U.S. ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 714 (10th Cir. 2006) ("mere knowledge of the submission of claims and knowledge of the falsity of those claims is insufficient to establish liability under the FCA"). Similarly, Relator alleges that "GHC instructed DxID" to code based on "incidental findings," AC ¶¶ 132-33, but fails to give any examples of coding for such claims or even to allege that DxID actually carried out this instruction. Nor does she cite any rule—regulatory, subregulatory, or otherwise—that prohibits coding for incidental findings.

condition associated with that diagnosis code was actively treated during the encounter in question. *See, e.g.*, AC ¶¶ 6, 50, 118, 141. Incorrectly treating the Participant Guide as if it were a formal regulation, Relator highlights two specific policies that she believes violated this "rule:" (1) submitting claims for past heart attacks ("old myocardial infarctions" or "old MIs") "so long as there was mention of an old MI at some point in the patient's chart, regardless of how long ago," *id.* ¶ 107; and (2) submitting risk-adjustment claims for hypoxemia "if COPD [Chronic Obstructive Pulmonary Disease] or emphysema is listed in [a patient's] active problem list" and the treating physician has "ordered [a prescription for] oxygen," *id.* ¶ 105.

But official ICD-9 Coding Guidelines—some of which are discussed in Relator's own exhibits—make clear that Relator's interpretation is mistaken. The relevant coding guidelines provide:

> Code 412, Old myocardial infarction, is a history code and should be reported to identify a "healed old MI" whether the patient is currently experiencing problems of [sic] not. An old myocardial infarction is coded because it is significant and affects the management of the patient. The note under code 412 mentioning, "currently presenting no symptoms" refers to symptoms related to the previous old myocardial infarction, not cardiac symptoms in general.

AC Ex. 2 at 15 (*quoting* ICD-9-CM Coding Clinic, Second Quarter 2003, Page 10); *see also* 2010 ICD-9 Guidelines at 68-69. In other words, "old MI" should be coded irrespective of whether the MI was recent or not, and irrespective of whether the patient received an active intervention for that MI during the visit in question.

This policy makes sense in the risk-adjustment context, because a history of heart attacks increases the frequency and severity of health conditions that the beneficiary will experience throughout his life. Accordingly, the Participant Training Guide itself explains that "[p]hysicians should code all documented conditions that co-exist at the time of the encounter/visit," so long as the condition still exists and is likely to have "an impact on current care or influence[] treatment."

Participant Training Guide at 6-5, 6-6. This is because "chronic, ongoing conditions such as diabetes, . . . heart failure, . . . [COPD,] and pulmonary disease," are "generally managed by ongoing medication and have the potential for acute exacerbations[.]" *Id*. at 6-6. Thus, even though these conditions "might not impact every minor healthcare episode," they typically are "documented and reportable," for each provider visit because a patient who has had these conditions requires different evaluation, treatment, and care than a patient who has not. *Id*.

The RADV Guide that CMS uses to instruct its own auditors drives this point home even further. That Guide begins by articulating the same "treatment" requirement on which Relator relies. 2011 RADV Guide at 4 (Meron Affirmation, Ex. A); *compare* AC ¶ 50. The RADV Guide then goes onto explain, however, that CMS interprets this "treatment" requirement very differently than does Relator in the context of "chronic" or ongoing conditions coded for risk adjustment purposes:

> [T]he coder should be aware of the background and prospective nature of the RA [risk-adjustment] payment process including its basis on chronic conditions, and dependence on validating chronic conditions for an annual payment on just the review of one record. It is **imperative** therefore to code all chronic conditions documented by an acceptable provider type during a face to face encounter with the patient, **whether or not there was specific treatment mentioned in the one record submitted**. **Mention or EMR [*i.e.*, automated electronic medical-record] population of the diagnoses narrative list can be interpreted as management and care for the applicable chronic conditions** of the patient once all other coding rules and checks for consistency have been applied. **This is where RADV [Risk Adjustment coding] audits may differ in guideline interpretation from fee-for-service**, DRG [diagnosis-related group] audits or others based on just the payment for one specific encounter.

2011 RADV Guide at 4 (emphasis added). In other words, a chronic or ongoing condition—including a history of heart attacks—is deemed to have been "treated" each time that condition is mentioned in a patient's medical record, even if that condition did not receive a dedicated intervention during the visit in question. CMS's RADV Guide thus makes clear that it is perfectly

appropriate to code chronic conditions (such as the ones that are the focus of Relator's complaint) whether or not the medical record shows that the patient received a specific treatment for that particular condition during the encounter. Relator's contrary view lacks support and, as illustrated by Relator's own exhibits, was not shared by most of her peers. *See* AC Ex. 4 at 3-4.

For similar reasons, Relator is wrong to assert that the Participant Training Guide bars MA plans from coding based on "problem lists" that appear in a patient's medical record. The term "problem list" does not have a "universal definition," but often refers to a stand-alone list "used by a coder to gain an overall clinical picture of a patient's condition(s)." Participant Training Guide at 7-17. Relator reads this section of the Participant Training Guide as suggesting that coding off of these lists is proper only when the patient received "evaluation and treatment" for the coded condition during the visit in question. *Id*. Again, her interpretation is wrong. As the overall context of this provision makes clear,[8] this limitation applies only to *stand-alone* problem lists; it does *not* apply to problem lists that are embedded within a medical record for a face-to-face encounter (as is the case here, where DxID was reviewing medical charts, not isolated documents, *see* AC ¶¶ 23, 92). That is precisely how CMS itself understands the relevant coding guidelines: it instructs its own coders that whereas "standalone" problem lists must "show evaluation and treatment" to support a code, "problem lists within an office record" may be used to support a diagnosis code so long as the conditions listed are chronic in nature and are not

[8] The provision itself notes that a "problem list" is sometimes, but not always, supported by "other medical record documentation." Participant Training Guide at 7-17. It is also noteworthy that this provision appears *not* in Chapter 6 of the Guide, which is the chapter dealing with coding criteria, but rather in Chapter 7, which is devoted to discussing the types of documentation that CMS utilizes when conducting its RADV audits. And the RADV audit guidelines make abundantly clear that CMS believes it is perfectly consistent with applicable coding guidelines to code based on problem lists that are embedded within a patient's medical record, without evidence of current treatment or other clinical indicia.

"inconsistent with the current encounter," "*whether or not specific and related treatment or medications are noted in the current encounter."* 2011 RADV Guide at 54-56 (emphasis added).

DxID proposed coding for hypoxemia—a condition characterized by low blood-oxygen levels—only if that condition was both (1) indicated on an "active" problem list contained in a "face-to-face encounter note," AC Ex. 2 at 16, and (2) the treating physician had also "ordered [a prescription for] oxygen." AC ¶ 105. As the above discussion makes clear, the first limitation perfectly comports with the coding guidelines discussed in the Participant Training Guide as CMS itself understands them, and the second limitation goes above and beyond even CMS's own proposed limitations.[9] The same is true for DxID's policy of coding for chronic kidney disease (CKD) so long as that diagnosis was "listed in the ACTIVE Problem list," and "embedded in an encounter note at a face-to-face encounter." AC Ex. 2 at 2 (capitalization in original). Relator is simply wrong to suggest that these coding policies were improper.

2. *Diagnostic Testing*. Relator also takes issue with DxID's proposed policy of submitting claims for old MIs that are supported by signed-and-dated electrocardiogram ("EKG") results. AC ¶ 107. Relator believes that "CMS coding rules" prohibit coding based only on diagnostic test results, such as EKGs, because those results are not the product of a face-to-face encounter (¶ 108).

Again, not only does Relator fail to point to any "rule" or regulation setting forth this alleged prohibition, but the plain text of the official ICD-9 Guidelines also contradicts Relator's view. Those Guidelines explain that it is appropriate to code based on diagnostic tests so long as those tests have "been interpreted by a physician," even if diagnostic testing was the only service

[9] With respect to the second limitation, Relator asserts that the provision of medical supplies and equipment, such as oxygen tanks, does not count as "treatment" in a way that would support a risk-adjustment claim, but she cites no support for this counterintuitive belief. AC ¶ 105.

that the patient received during the relevant "encounter/visit." AC Ex. 2 at 15 (*quoting* 2002 ICD-9 Guidelines at 51); *accord* 2010 ICD-9 Guidelines at 93.

Indeed, CMS's own internal interpretation of the ICD-9 Guidelines lists EKGs as an "acceptable example" of documentation sufficient to support a risk-adjustment claim for a heart attack, so long as the EKG has been interpreted by a provider. 2011 RADV Guide at 45. This is true even if the EKG was unaccompanied by any "interventional procedures." *Id*. The RADV Guide notes that, generally, a face-to-face visit is required, but explains that this requirement is satisfied in the context of "diagnostic testing," such as EKGs, so long as that testing is accompanied by "acceptable provider interpretation" (i.e., so long as the coder is "abstract[ing the] diagnoses from the physician interpretation, not [from the raw results of the] technical report"). *Id*. at 47. DxID's proposed policy of coding for old MIs that had been definitively confirmed in a "signed and dated EKG" (AC Ex. 2 at 3)—i.e., an EKG reviewed, signed, and attested to by a physician—absolutely comports with this requirement.

3. *Physician query forms*. Finally, Relator alleges that DxID and Independent Health employed "physician 'queries' and addenda to medical records," in which they asked physicians to clarify diagnosis codes after the date of service. AC ¶¶ 153-58. Relator, however, does not cite a single statute, regulation, or even informal guidance document prohibiting use of queries and addenda, or so much as addressing the criteria for their use. That failure alone is fatal.

While Relator believes that use of query forms "pressure[s] physicians to improperly amend medical records," AC ¶ 158, her Amended Complaint contains no factual basis for this proposition at all, let alone particularized factual allegations. Indeed, the exhibits attached to the Amended Complaint illustrate the absurdity of Relator's allegation. Those exhibits show DxID used queries to obtain confirmation of only those diagnoses that are strongly suggested by "clinical

indicators." AC Ex. 5 at 3. These forms "do not lead the physician," *id.*, and—contrary to Relator's assertion—do not tell the physician that DxID or the health plan believes that the patient has certain conditions, AC ¶ 156. *See* AC Ex. 6 (copy of addendum form). Use of these forms was not improper, let alone unlawful.

2. At the very least, Defendants' conduct was consistent with an objectively reasonable understanding of the coding guidelines.

For the reasons explained above, DxID's alleged coding policies fully comport with the CMS's own understanding of the introductory coding training provided in the Participant Training Guide. Indeed, each coding policy was designed to accurately and faithfully capture the health status of patients. But this Court does not need to definitively resolve the meaning of every guideline provision cited by Relator in order to resolve this Motion. It is enough for the Court to note that DxID's interpretation of the relevant guidance documents was objectively reasonable.

For all the reasons discussed above, *see supra* Part IV.B.1, the interpretations of the relevant coding guidelines adopted by GHC and recommended by DxID were—at an absolute minimum—objectively reasonable. The FCA is a fraud statute—not a strict liability or negligence statute—and so it does not penalize individuals for acting in accordance with objectively "reasonable but erroneous interpretations of [their] legal obligations." *Purcell*, 807 F.3d at 288; *see also Allergan*, 746 F. App'x at 106 (same); *U.S. ex rel. Donegan v. Anesthesia Assocs. of Kansas City, PC*, 833 F.3d 874, 880 (8th Cir. 2016). In related contexts, the Supreme Court has explained that where a statute requires a "knowing" or "reckless" mental state—as does the FCA—"Congress could not have intended [to impose liability] for those who followed an interpretation that could reasonably have found support in the courts, whatever their subjective intent may have been." *Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 70 n.20 (2007).

Courts, in accordance with this precedent, routinely dismiss FCA suits like this one that turn on the proper interpretation of ambiguous language. *See, e.g., Allergan*, 746 F. App'x at 109-10; *U.S. ex rel. Grupp v. DHL Exp. (USA), Inc*., 47 F. Supp. 3d 171, 177 (W.D.N.Y. 2014) ("a defendant's reasonable interpretation of its legal obligation precludes a finding that the defendant had knowledge of its falsity") (quotation marks and citations omitted), *aff'd* 604 F. App'x 40 (2d Cir. 2015); *Grupp*, 47 F. Supp. 3d. at 179 ("No additional detail [could] transform this contract ambiguity into a fraud claim."); *U.S. ex rel. Wilson v. Kellogg Brown & Root, Inc*., 525 F.3d 370, 378 (4th Cir. 2008) ("An FCA relator cannot base a fraud claim on nothing more than his own interpretation of an imprecise [] provision."); *U.S. ex rel. Colucci v. Beth Israel Med. Ctr.*, 785 F. Supp. 2d 303, 316 (S.D.N.Y. 2011) ("Even assuming [their claims] were 'false,' given the lack of clarity in the law, it cannot be said that defendants 'knew' the claims were false."); *id*. at 314 ("The worst that can be said of [defendant] is that it took advantage of the uncertainty in the regulations to maximize its Medicare billings. This is not fraud."). This Court should do the same.

C. Relator Fails to Allege That the Challenged Conduct Was Material to The Government's Decision to Pay

In addition to its numerous other defects, the Amended Complaint fails adequately to plead that Defendants' failure to comply with Relator's interpretation of coding guidelines constitutes "material" misconduct. *See Grabcheski*, 687 F. App'x at 87 ("Materiality must be pleaded with particularity under Rule 9(b).").

The FCA's "materiality standard is demanding," *Universal Health Serv*., 136 S. Ct. at 2003, and requires a relator to allege *particularized* facts showing that the supposed violations "are so central . . . that the [government] *would not have paid these claims* had it known of these violations." *Id*. at 2004 (emphasis added); *Coyne*, 717 F. App'x at 28–29 ("to be material the

government must have made the payment 'as a result of the defendant's alleged misconduct'") (*quoting U.S. ex rel. Ge v. Takeda Pharm. Co. Ltd*., 737 F.3d 116, 124 (1st Cir. 2013)); *Mikes*, 274 F.3d at 696 ("a claim is 'false' only if the Government or other customer would not pay the claim if the facts about the misconduct alleged to have occurred were known"). The Supreme Court has admonished that this standard should be applied even at the motion to dismiss stage. *Universal Health Serv*., 136 S. Ct. at 2004 n.6 ("We reject [the] assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment."). The Amended Complaint utterly fails this test in several ways.

First, although it contains a barebones, conclusory assertion of materiality (*see* AC ¶ 166), the Amended Complaint does not allege that CMS *ever* failed to pay a risk adjustment claim as a result of the conduct Relator complains about. This failure is especially revealing in the context of this case, where the government spent over seven years investigating Relator's allegations and declined to intervene. Indeed, Relator alleges that she gave the government "specific identifying information" regarding four specific claims for reimbursement that she believes were "false" within the meaning of the FCA. AC ¶ 140. She does not, however, plead that the government ever sought reimbursement from GHC for any of these four claims. This omission, coupled with the fact that the government has declined to intervene in this suit, raises serious doubts that Relator could plead materiality even if given leave to amend.

Second, despite alleging a smattering of "specific" instances in which GHC submitted claims that were not adequately supported (AC ¶¶ 140-47), Relator conspicuously fails to allege that there were no other encounters within the same year that *did* support that same diagnosis code. The failure to include such an allegation undermines her claims, because if any other such diagnosis codes did exist, they would make the lack of medical record support in the specific chart

on which her claims are focused immaterial. *See* FFS Study Executive Summary, *supra* n.1, at 3 (explaining that CMS will validate a risk-adjustment claim for a given patient so long as "at least one" diagnosis code for that patient is supported, even if all other entries of the same diagnosis code are unsupported). Moreover, with respect to defendant IHA (or, for that matter, IHC), the Amended Complaint does not contain even a single example of an unsupported diagnosis code.

Third, and just as fundamentally, Relator fails to plead that the alleged "error rate" in either GHC's or IHA's risk-adjustment coding exceeds the error rate in traditional Medicare. This is a fatal defect because the Medicare Act requires CMS to (1) ensure that there is "actuarial equivalence" between the traditional fee-for-service Medicare program and the Medicare Advantage program, 42 U.S.C. § 1395w-23(a)(l)(C)(i), and (2) "us[e] the same methodology" when calculating the risk that patients present in both the MA and traditional Medicare programs, *id*. § 1395w-23(b)(4). Requiring MA plans to delete every diagnosis code they determine was unsupported or "should have known" was unsupported, without adjusting for the presence of such codes in CMS's own traditional Medicare data—which CMS recently estimated to be as high as 34 percent[10]—would violate both of those requirements. *See UnitedHealthcare Ins*., 330 F. Supp. 3d at 184-87. By failing to allege that the overall error rate in GHC's claim submissions (let alone Independent Health Association's submissions) exceeds this error rate, Relator has failed to plead that the errors caused a cognizable overpayment, and thus failed to plead that those errors are "material."

[10] *See* CMS, *Fee for Service Adjuster and Payment Recovery for Contract Level Risk Adjustment Data Validation Audits – Technical Appendix*, at 6, Table 2a, https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-Risk-Adjustment-Data-Validation-Program/Other-Content-Types/RADV-Docs/FFS-Adjuster-Technical-Appendix.pdf.

Fourth, even apart from these fundamental pleading deficiencies, there are substantive reasons to doubt that GHC and DxID's coding policies were material. That is because—as discussed above (*supra* Part IV.B.1)—the coding criteria Relator claims to be inconsistent with the Participant Training Guide are used by CMS coders *themselves* when they review a plan's codes to determine if payment was appropriate.

For example, Relator claims that CMS coding rules require "active treatment" in the form of an intervention to support entry of a diagnosis code, and likewise contends that problem lists are "invalid" and can never support a risk-adjustment diagnosis code unless the problem list shows evidence the condition was treated during that same encounter. AC ¶¶ 6, 97, 118. However, CMS's own internal risk-adjustment audit guidelines take the *opposite* view: "It is imperative [] to code all chronic conditions documented by an acceptable provider during a face-to-face visit, *whether or not there was specific treatment mentioned in the one record submitted*." 2011 RADV Guide at 5 (Meron Affirmation, Ex. A) (emphasis added). This is true even if the condition appears *only in a problem list or snapshot that is* "autofilled into the current encounter template," so long as "other coding rules and checks for consistency have been applied."[11] *Id*. CMS explains that this is one area where "[risk-adjustment guidelines] may differ in guideline interpretation from fee-for-service [guidelines]," because the goal in risk-adjustment coding is to capture "all chronic conditions" that might affect a patient's risk score, and not simply to record the treatment that the

[11] As noted earlier, the 2011 RADV Guide discussion of problem lists contained within a medical record likewise states that "chronic" conditions that "are not inconsistent with the current encounter . . . should be coded *whether or not specific and related treatment or medications are noted in the current encounter." Id*. at 55-56 (Meron Affirmation, Ex. A) (emphasis added). Indeed, the RADV Guide goes even further and states that the "presence of a statement 'not reviewed' or similar note does not preclude the reporting of the chronic condition." *Id.*

patient received. *Id*. This is precisely how GHC and DxID approached risk-adjustment coding.[12]

The alleged coding policies that Relator challenges cannot have been "materially" fraudulent when CMS instructed its *own auditors* to assess the validity of diagnosis codes based on the same criteria, and to uphold risk-adjustment payments for any codes that conform to those criteria. On the contrary, CMS's RADV Guide indicates that if CMS were to conduct an audit of these claims, it would validate the relevant codes and not seek to recover any payments. At a minimum, this makes it all the more important to insist on Relator pleading particularized facts to support her claim that CMS would in fact not have paid defendants had it been aware that they were allegedly employing the coding criteria Relator criticizes.

D. Relator Fails to Plead Fraud with Particularity

Apart from the fact that Defendants' conduct was objectively reasonable, Relator's claims against DxID, Independent Health, and the Individual Defendants fail for the additional reason that the Amended Complaint lacks the particularized allegations of either falsity or of intent that Rule 9(b) demands in a fraud case such as this one. Rule 9(b)'s "stringent pleading requirements," *Grandon v. Merrill Lynch & Co*., 147 F.3d 184, 188 (2d Cir. 1998), are designed to prevent plaintiffs with no firsthand knowledge of fraud from obtaining discovery to fish for "unknown wrongs," *Madonna*, 878 F.2d at 66 (internal quotation marks omitted).

To satisfy Rule 9(b) in the context of the False Claims Act, a complaint must "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *Ladas,* 824 F.3d at 25 (internal citation omitted); *accord Johnson*, 686 F. Supp. 2d at 268 ("in order to

[12] Likewise, GHC and DxID approached coding for diagnostic testing in the same way that CMS's own auditors were instructed to. *See supra*, Part IV.B.1.

allege fraud with particularity, a claim must include more specific details, such as the persons, amounts, dates and other facts relating to the alleged false claims"). It is not enough to provide a "'rough sketch' of fraud," *id.*, nor is it permissible to lump multiple defendants together under a "guilt by association" theory, *United States v. Strock*, No. 15-CV-0887, 2019 WL 4640687, at *5-6 (W.D.N.Y. Sept. 24, 2017). The Amended Complaint falls woefully short of this standard.

1. Relator pleads no facts suggesting that either Independent Health entity or the Individual Defendants engaged in *any* misconduct.

With respect to the Individual Defendants, Relator's Amended Complaint contains no substantive allegations whatsoever. She provides no details about Ms. Gaffney or Dr. Haughton's alleged role in the events described in the Amended Complaint, and instead simply declares that both individuals are interchangeable with DxID. AC ¶ 28. Indeed, the only times the Amended Complaint even *mentions* either Gaffney or Haughton are (1) in the paragraphs listing the "identity of the defendants," *id.* ¶¶ 26-28, and (2) in the prayer for relief, *id.* at 55.

This is grossly deficient. In order to establish individual liability under Rule 9(b), it is not enough to plead that an individual worked for a company accused of violating the False Claims Act. Rather, a complaint must plead, with particularity, facts giving rise to liability "for *each* defendant; guilt by association is impermissible." *Strock*, 2019 WL 4640687, at *5-6 (*quoting In re DDAVP Direct Purchaser Antitrust Litig*., 585 F.3d 677, 695 (2d Cir. 2009)) (emphasis added). "Without knowing exactly what [an individual defendant] is alleged to have represented and when," it is impossible plausibly to infer that the defendant "knew her representations were false." *Id.* at *6. "This is why Rule 9(b) requires a fraud complaint to specify the fraudulent statements, identify the speaker, state where and when the statements were made, and explain why the statements were fraudulent." *Id*. Relator makes no attempt to do any of those things here.

Relator's allegations against the two Independent Health entities fare no better. Relator does not claim to have personal knowledge of *anything* related to either entity, and offers no particularized allegations about Independent Health's beneficiaries, the coding policies either entity chose to adopt or approve, or even a single diagnosis code either entity has submitted to CMS. All she offers is a couple of paragraphs' worth of conjecture that because DxID is a subsidiary of Independent Health Corporation and allegedly provides coding advice to one of the two Independent Health entities (she does not even specify which), "it is highly likely the algorithms and procedures DxID used to review IH's risk adjustment claims are the same as the procedures used to review GHC's claims." AC ¶ 152.

This is an archetypal example of the type of rank "speculation" that Rule 9(b) was designed to prevent.[13] *Fogel v. Vega*, 759 F. App'x 18, 25 (2d Cir. 2018) (*quoting Wexner v. First Manhattan Co*., 902 F.2d 169, 172 (2d Cir. 1990)); *see also U.S. ex rel. Schaengold v. Mem'l Health, Inc*., No. 4-11-cv-58, 2014 WL 6908856, at *12 (S.D. Ga. Dec. 8, 2014) ("merely being a parent, or an associated corporation, of a subsidiary that commits an FCA violation is insufficient to support an FCA action") (*citing U.S. ex rel. Hockett v. Columbia/HCA Healthcare Corp*., 498 F. Supp. 2d 25, 59-60 (D.D.C. 2007)).

These speculations about the Independent Health entities are particularly insufficient in the context of this case, where Relator herself admits that DxID never implemented its coding policies directly. Instead, DxID would make certain proposals to its clients, like GHC, which the client would then have the sole authority to "approve or reject." AC ¶ 99; *see also id*. ¶ 137 (explaining

[13] Along these same lines, Relator surmises, based on hearsay, that Independent Health, at DxID's urging, may have "pressure[d]" physicians to improperly document conditions that were not reflected in their medical records—but points to no instances in which this supposedly occurred, no doctors who supposedly were subjected to, much less succumbed, to this alleged "pressure," and no specific documents that bear any hallmarks of coercion. *See* AC ¶¶ 158-59.

that GHC *rejected* one of DxID's proposed policies). Even if some of the coding proposals that DxID recommended to GHC were improper (which they were not), Relator has failed to plead any facts suggesting that Independent Health actually approved or adopted them for use on its beneficiaries, or what conditions it may have placed on their use. Not even the ordinary pleading requirements of Rule 12(b)(6) would allow a claim to go forward based on such naked conjecture. *See Twombly*, 550 U.S. at 555 ("Factual allegations must be enough to raise a right to relief above the speculative level[.]").

2. Relator does not adequately plead that DxID, the Individual Defendants, or either Independent Health entity acted with fraudulent intent.

Under the FCA, a plaintiff must "allege facts that give rise to a *strong* inference of fraudulent intent." *Grubea*, 318 F. Supp. 3d at 694; *Tessler*, 712 F. App'x at 29 ("FCA complaints are subject to Federal Rule of Civil Procedure 9(b) . . . . [which] permits scienter to be averred generally, but 'we have repeatedly required plaintiffs to plead the factual basis which gives rise to a strong inference of fraudulent intent.'"). Here, Relator—who had no interaction at all with Independent Health, and limited, if any, direct interaction with DxID—points to no facts whatsoever that would support a strong inference that those defendants acted with the requisite fraudulent intent.

For example, Relator says she advised GHC that she thought DxID's coding policies were unlawful, but nowhere alleges that she informed *DxID* (let alone either Independent Health entity or either of the Individual Defendants) of that view or—more importantly—that anyone at DxID agreed with her view and recognized that its proposed coding practices were improper. Nor could Relator make such allegations. As discussed above, the coding guidance on which Relator's claims are based has been issued through informal mechanisms and leaves room for reasonable professionals to disagree about their meaning and application. CMS itself recognizes that

numerous coding issues are not covered by the official ICD-9 Guidelines and therefore "require reviewer discretion." 2011 RADV Guide at 21 (Meron Affirmation, Ex. A). On most of these judgement calls, moreover, CMS audit training guides side with DxID's understanding of applicable coding criteria, not with Relator's. *See supra* Parts IV.B-C.

Relator's own allegations and the materials attached to her Amended Complaint make clear that the question of how properly to code certain diagnoses generated lengthy academic debates, both within GHC and between GHC and DxID personnel. For example, Relator's claims are premised in large part on notes from a December 2011 conference call between GHC and DxID employees, in which Relator claims that one GHC employee, Rhona Moses, exposed DxID's "unlawful" coding practices to GHC. AC ¶¶ 100-09. The notes from this call, however, do not even remotely support Relator's characterization of that conversation. Instead, the notes depict a good-faith, back-and-forth technical debate between industry experts about how to best interpret coding guidance from a variety of different, subregulatory sources. While there were a handful of instances in which Moses disagreed with DxID's interpretation of guidance documents, the call notes make clear that Moses's view was a minority even within her own company. *See*, AC Ex. 4 at 3 (noting that Dr. Tarnoff, GHC's Associate Medical Director, agreed that DxID's interpretation of guidelines surrounding the coding of old MIs was correct and that Moses's interpretation was erroneous). Contrary to Relator's insinuations, at no point in the phone call did Moses accuse DxID of fraud or "unlawful" practices; on the contrary, she acknowledged that DxID's coding practices "*would be defensible*" and "*supportable on appeal*," even though in some instances she personally "would not code off of th[em]." *Id*. at 5 (emphases added). These types of interpretive debates illustrate academic and professional disagreement, but they do not suggest fraud. Relator

has pled absolutely no facts suggesting—much less creating a strong inference—that DxID did not adopt its coding criteria in good faith, or that its reliance on those coding criteria was reckless.[14]

Relator has even less basis for making such claims about either the Independent Health entities or the Individual Defendants, as to whose intent she does not provide any particularized allegations at all. At the end of the day, even if one of the Independent Health entities did follow the coding advice of DxID—which employed trained and certified diagnostic coders—believing the advice to be proper, it may at worst have made a mistake, but it did not commit fraud.

V. CONCLUSION

For the reasons stated above, this Court should dismiss Relator's claims with prejudice.

[14] Relator fails to plead fraudulent intent even with respect to the four "specific" examples of false claims that she alleges DxID submitted on GHC's behalf. AC ¶¶ 140-47. Based on Relator's descriptions, these four examples would not appear to be supported even under DxID's own proposed policies. *See* AC ¶¶ 143-44, 146 (describing instances in which DxID allegedly submitted claims for diagnoses that had either been "resolved" or ruled out); *id*. at ¶ 147 (describing an instance in which DxID allegedly coded based on an EKG that may not have been signed and attested to by a physician). Nothing in the Amended Complaint suggests these four instances were attributable to anything other than unintentional human error, of the sort that CMS itself recognizes is exceedingly common in diagnostic coding (*see supra*, Part IV.C (noting that CMS estimates its own rate of unsupported conditions to be approximately 34 percent)).

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Respectfully submitted,

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